

#### **DETAILED ACTION**

1. Claims 12, 13, 22, and 23 are pending and under consideration.

#### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peilin Tan-Aquino, Reg. No. 59,280, on 7 April 2008.

The application has been amended as follows:

#### **IN THE CLAIMS:**

Claims 1-11. **(Cancelled)**

**12. (Currently Amended)** A method for treating or ~~preventing~~ an autoimmune disease or an autoimmune disorder comprising administering an effective amount of a ~~pharmaceutical composition and/or immune modulator composition~~ comprising a whole cell of a bacterium from one or more of the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*, *Tsukamurella* and *Nocardioide*s to a subject wherein said composition modulates a cellular immune response, and wherein the autoimmune disease or autoimmune disorder involves inflammation of the intima of a blood vessel and is a vascular disorder selected from the group consisting of atheroma formation (otherwise known as arteriosclerosis), myointimal hyperplasia

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(natural or following angioplasty), inflammatory and autoimmune thickening of the intima and/or muscular layer of blood vessels and myocarditis.

**13. (Currently Amended)** A method for ~~immunizing~~ immune modulation of a subject against an autoimmune disease or an autoimmune disorder comprising administering a ~~pharmaceutical composition and/or immune modulator composition~~ comprising a whole cell of a bacterium from one or more of the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*, *Tsukamurella* and *Nocardioideis* and wherein the autoimmune disease or autoimmune disorder involves inflammation of the intima of a blood vessel and is a vascular disorder selected from the group consisting of atheroma formation (otherwise known as arteriosclerosis), myointimal hyperplasia (natural or following angioplasty), inflammatory and autoimmune thickening of the intima and/or muscular layer of blood vessels and myocarditis.

Claims 14-21. **(Cancelled)**

**22. (Previously Presented)** A method according to claim 12 or claim 13 wherein said bacterium is selected from one or more of the group consisting of *Gordoniz bronchialis*, *Gordonia amarae*, *Gordonia sputi*, *Gordonia terrae*, *Nocardia asteroides*, *Dietzia maris*, *Tsukamurella paurometabola*, *Rhodococcus ruber*, *Rhodococcus rhodnii*, *Rhodococcus coprophilus*, *Rhodococcus opacus*, *Rhodococcus erythopolis*, *Nocardioideis albus* and *Tsukamurella inchenensis*.

**23. (Previously Presented)** A method according to claim 12 or claim 13 wherein said bacterium is killed.

Claims 24-25 **(Cancelled)**

**26. (New)** The method according to claim 12 or claim 13 wherein said composition is a pharmaceutical composition.

**27. (New)** The method according to claim 22 wherein said composition is a pharmaceutical composition.

**28. (New)** The method according to claim 23 wherein said composition is a pharmaceutical composition.

**29. (New)** The method according to claim 12 or claim 13 wherein said composition is an immune modulator composition.

**30. (New)** The method according to claim 22 wherein said composition is an immune modulator composition.

**31. (New)** The method according to claim 23 wherein said composition is an immune modulator composition.

### **Rejections Withdrawn**

3. The rejection of claims 12, 13, 22, and 23 under 35 U.S.C. 112, first paragraph, scope of enablement for the method for treating or preventing any/all autoimmune diseases or disorders, is withdrawn in light of the amendment of the claims.

The amendment of claim 12 to recite now a method of treating, coupled with the restriction that the autoimmune disease or disorder being treated involve inflammation of the intima and is a particular vascular disorder chosen from a list of vascular disorders, obviates the rejection which was based upon the wording of preventing autoimmune disease or autoimmune disorder.

The amendment of claim 13 to recite now a method of immune modulation of a subject against an autoimmune disease or disorder, coupled with the restriction that the autoimmune disease or disorder being treated involve inflammation of the intima and is a particular vascular disorder chosen from a list of vascular disorders, obviates the rejection which was based upon the wording of immunizing, i.e., preventing, an autoimmune disease or autoimmune disorder.

### **Conclusion**

4. Claims 12, 13, 22, 23, and 26-31 are allowed.

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 7, 2008